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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,614	08/11/2003	Katherine S. Tweden	7883.97-02	5399

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/639,614	TWEDEN ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-49,51-60 and 62-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-49,51-60 and 62-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-49,51-60,62-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for applying a covering to both an end inner surface portion and an end outer surface portion of the stent, does not reasonably provide enablement for applying the covering to both central inner and outer portions of the stent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claims are not limited to forming the end portion covering by folding over an end of the covering from the inner portion of the stent to the outer portion of the stent. However, the written disclosure and the drawings do not describe or show that a covering is applied anywhere else but the end. Thus, the application of a covering to an end of the stent and by folding over the covering from the inner surface is the only supported language that is enabled. The application of the covering to any portion of the stent's inner and outer surface is clearly unsupported.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 62-64,66,68 are rejected under 35 U.S.C. 102(a) as being anticipated by Sogard et al. (WO 98/12990). Fig. 3 shows a stent **10** having an outer surface with a covering **14** and Fig. 4 illustrates the inner surface can also have a covering **17**. In Fig. 6, Sogard shows both surfaces are covered. Sogard also discloses that an agent may be used with the stent, page 13, lines 9-13. Sogard additionally discloses the covering is ePTFE, page 12, lines 13-24. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Clearly, the device is capable of providing blood flow from a heart chamber to a coronary vessel. Sogard illustrates (Fig. 1) that the stent has bends in its design along the longitudinal axis.

Claims 62-68,70-72,74-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Buirge et al. (5693085). Buirge shows (Figs. 1,4,5) stents having bends in the structure and an open construction along the longitudinal axis of the stent. Buirge also discloses the stents are covered on both surfaces, col. 7, lines 26-28. Buirge additionally teaches that the coverings can include agents, such as heparin, col. 5, lines 30-32,41-48. Buirge discloses the covering can include PTFE, col. 9, lines 30-34. Fig.

6 shows that the stent can extend at an angle or that the two ends are not aligned. It is inherent that there is a transition portion between these two ends.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 65,67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sogard et al. (WO 98/12990) in view of Tartaglia et al. (5637113). Sogard is explained supra. However, Sogard fails to disclose the agent used with the stent is heparin. Tartaglia et al. teach the use of heparin with a covered stent, col. 6, lines 1-4. It would have been obvious to one of ordinary skill in the art to use heparin with the polymer as taught by Tartaglia in the stent of Sogard such that it prevents restenosis and thrombosis or clotting.

Claims 41,43,47-49,51-53,55,58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5429144) in view of Knudson et al. (5755682). Wilk discloses a stent placed in a myocardial site in the compressed state and then expanding the stent, col. 1, lines 54-63. Wilk also discloses (col. 8, lines 48-55) the stent has an inner and outer covering of natural tissue, Figs. 8A,8B,9. Wilk additionally discloses the method is used for passage of blood from the left ventricle to the coronary artery, col. 5, lines 46-48,53-56. Wilk also discloses deploying the stent by catheter, i.e. percutaneous, col. 6, lines 24-34. However, Wilk fails to disclose an agent is used with the stent to limit

thrombus formation. Knudson et al. teach that coating the stent with agents reduces restenosis, col. 10, lines 5-9. The Examiner also interprets a coating on the stent to be all surfaces, see Buirge '085. Since the agent is to prevent restenosis, it can be construed that the agent limits thrombus formation. Restenosis is a re-narrowing or blockage of an artery caused by a build-up of substances, i.e. blood clotting, platelets, that may eventually block the flow of blood. It would have been obvious to one of ordinary skill in the art to use an agent with a covering on both an inner surface and outer surface portion of the stent as taught by Knudson with the stent of Wilk such that it prevents restenosis and thrombus formation.

Claims 41-49,51-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5429144) in view of Lee (5123917). Wilk is explained supra. However, Wilk fails to disclose an agent, such as heparin to be used with the stent to limit thrombus formation or explicitly that the covering is on both surfaces of the stent . Lee teaches that agents such as heparin are used with a PTFE graft-stent to limit thrombus formation, col. 4, lines 51-61. Lee shows (Fig. 4) that the stent includes coverings on both inner and outer surfaces. Lee also discloses the use of the inner and outer coverings secure the stent with coverings and together provide a supportive replacement, col. 3, lines 1-24. It would have been obvious to one of ordinary skill in the art to use the heparin stent-graft of PTFE and an outer covering also as taught by Lee in the method of Wilk such that it provides a graft that does not promote intimal tissue proliferation and limits thrombus formation, while also providing a smoother outer surface to contact the vessel wall by applying an outer covering also taught by Lee.

Claims 69,73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buirge et al. '085 in view of Knudson et al. (5755682). Buirge does disclose the stent is placed in an artery, col. 7, lines 21,22 and can have a fixed diameter, col. 9, lines 3-6. Buirge is explained supra. However, Buirge fails to disclose the stent is bent at 90 degrees to form an L-shape. Knudson et al. teach that the L-shape is useful in bypassing an obstruction in an artery, with one end placed in the artery and the other in a heart chamber, col. 13, lines 55-65. It would have been obvious to one of ordinary skill in the art to form the bend of the stent at 90 degrees or L-shape as taught by Knudson et al. with the stent of Buirge et al. in order to bypass a clot or obstruction in an artery and provide a passage directly to the heart chamber for direct blood flow.

Response to Arguments

Applicant's arguments filed 2/6/06 have been fully considered but they are not persuasive. Applicant continues to argue that Sogard fails to disclose a stent capable of the intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Additionally, Applicant argues that Sogard's stent does not include a bend. However, this is not true because claims are given their broadest reasonable interpretation and as shown in the drawings, there are bends in the stent structures of Sogard's stent. Applicant also argues that Wilk does not disclose the stent has coverings on both inner and outer surface portions of

the stent. However, as noted above Knudson discloses coatings on the stent and Lee also teaches that coverings are placed on both the inner and outer surfaces of the stent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian Pellegrino

BRIAN E. PELLEGRINO
PRIMARY EXAMINER